UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Friday, May 04, 2007

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 74986-4/Selective Micro Clean- Alpha

DP Barcode: D337168

To: Emily Mitchell, PM 32/ Wanda Henson
Regulatory Management Branch
Antimicrobials Division (7510C)

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Through: Karen Hicks, Team Leader
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Applicant: Selective Micro Technologies, LLC

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Sodium chlorite	30.50
Other Ingredient(s):	69.50
Total:	100.00

1) BACKGROUND: Selective Micro Technologies, LLC, has submitted a response to a previous CTT/PSB review of their product, "Selective Micro Clean Alpha".

The results of the last review of this product were:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	463908-01	III	Acceptable
Acute Dermal Toxicity	463908-02	IV	Acceptable
Acute Inhalation Toxicity	None		Data Gap
Primary Eye Irritation	463908-06	I	Cited
Primary Skin Irritation	463908-03	I	Acceptable
Dermal Sensitization	None	Nonsensitizer	Waived

a) This submission includes a January 2007 document entitled "**Attachment B**, Response to Ian Blackwell's questions on Test Substances". This volume states that the registrant wishes to support 74986-4 by bridging from 74986-1 to 74986-4.

b) This submission also includes an acute oral toxicity study: MRID Number 470510-01. This study is apparently a resubmission of an acute oral toxicity study that was previously reviewed for another Selective Micro Technologies product. The registrant's transmittal letter states: "For the acute oral data requirement, we are submitting with this package a new study (PSL Report #11925) conducted using the activated solution from EPA Reg. No. 74986-1..."

c) MRID Number 470339-02: The registrant requests a waiver of the acute dermal toxicity study due to the packaging of the product.

1) RECOMMENDATIONS: PSB findings are:

a) The consultant has submitted acute oral toxicity studies for 74986-4 and 74986-5. The MRID Numbers are 470510-01 and 470511-01, respectively. While these reports list different EPA File Symbols, both these reports:

i) Were conducted by the same lab.
ii) Have the same lab study number, 11925.
iii) Have the same study completion date.
iv) Have the same test material, Selective Micro Clean 2L500.

v) Have the same PSL Reference Number, 020318-2D.

The registrant and consultant should not take one study report, add a different EPA File Symbol and submit it as two new reports. In addition, CTT believes that this same study was previously submitted and reviewed for 74986-1.

b) CTT denies the request to bridge acute oral toxicity data from 74986-1 to support 74986-4. The reasons for the denial are:

i) The registrant has already submitted an acute oral toxicity study to support 74986-4. That study was conducted on **74986-4**.
ii) MRID Number 470339-02 (the waiver request for the acute dermal toxicity study) states that 74986-1 and 74986-4 are "identical products except for the external packaging". Based upon that statement, the two products should give the same results in an acute oral toxicity study. This is not the case. Reg. No. 74986-1 achieved toxicity category IV for acute oral toxicity; however, 74986-4 falls into toxicity category III for acute oral toxicity.
iii) Due to the unique packaging of this product, the registrant is hoping to cite data used on the **use-dilution** of 74986-1. However, in order to make this decision, CTT will need:

(1) The product chemistry reports and reviews that describe or compare the chemical composition of the use-dilutions of 74986-1 and 74986-4.
(2) Samples of the product packaging of 74986-1 and 74986-4.

c) CTT denies the waiver of the acute dermal toxicity study for 74986-4. The reasons for this denial are that the registrant has not presented enough information on the packaging of 74986-4. Should the registrant want to pursue this waiver, we will need:

i) The product chemistry reports and reviews that describe or compare the chemical composition of the use-dilutions of 74986-1 and 74986-4.
ii) Samples of the product packaging of 74986-1 and 74986-4.

CTT has already assigned this product toxicity category IV based upon an acute toxicity study conducted on the powdered version of 74986-4 as opposed to the use-dilution. If the registrant were granted a waiver of the acute dermal toxicity study, the product would still be assigned toxicity category IV.

d) CTT does not have enough information to assess the request for a waiver of the acute inhalation toxicity study. For us to properly assess the request of an acute inhalation toxicity study for 74986-4, we need:

i) The product chemistry reports and reviews that describe or compare the chemical composition of the use-dilutions of 74986-1 and 74986-4.
ii) Samples of the product packaging of 74986-1 and 74986-4.
iii) To take those product chemistry reports and reviews to HED and/or RD acute inhalation toxicity specialists for review.
iv) To take those product chemistry reports and reviews to AD exposure specialists for review.

The acute toxicity profile for File Symbol 74986-4 is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	463908-01	III	Acceptable
Acute Dermal Toxicity	463908-02	IV	Acceptable
Acute Inhalation Toxicity		?	Data Gap
Primary Eye Irritation	457782-06	I	Cited
Primary Skin Irritation	463908-03	I	Acceptable
Dermal Sensitization	None	Nonsensitizer	Waived

2) LABELING:

a) The signal word is "DANGER".

b) No other precautionary statements or First Aid statements can be recommended at this time.